## Remarks/Arguments

A petition for a 3-month extension of time is enclosed herewith.

Rejection Under 35 USC 112

Claims 57, 58, 65, 69, 72 and 73 have been rejected under 35 USC 112 for indefiniteness due to certain recitations in the claims. The claims have been amended remove the recitations that gave rise to the present rejection and withdrawal of this ground of rejection under 35 USC 112 is respectfully requested.

Rejections Under 35 USC 103

56-70, 75 and 77 are rejected under 35 USC 103 as obvious over Balkan et al. (WO 01/528825 A2). The rejection is respectfully traversed. Balkan et al. discloses (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine (LAF237) (page 6 lines 10-12) and that pharmaceutical preparations for oral use can be obtained by combining the active ingredient with solid carriers, if desired granulating a mixture obtained, and processing the mixture or granules, if desired or necessary, after addition of suitable excipients to give tablet or sugar-coated tablet cores. Example 1 cited on pages 37 and 38 is not relevant to the obviousness rejection since they are directed to tablets of *nateglinide*, not (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine. Further, there are no teaching in Balkan et al. that would suggest to one skilled in the art to Applicants' claimed compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet, wherein the dispersion contains particles comprising a DPP-IV inhibitor which is (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form, *and wherein at least 60% of the particle size distribution in the tablet is less than 250 µm*. In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. *See* MPEP 2141(II). With this framework in mind, Balkan et al. would not have been understood by the person of ordinary skill as making obvious the addition of (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form, and wherein at least 60% of the particle size distribution in the tablet is less than 250 µm. Accordingly, Balkan et al. does not support *a prima facie* case of

obviousness under 35 USC 103(c) and withdrawal of this ground of rejection is respectfully requested.

Claims 71-74 are rejected under 35 USC 103(a) as obvious over Balkan et al. (WO 01/528825 A2) in view of Burgess et al. (US 2004/0186046 A1) The rejection fails for the same reasons discussed above for Balkan et al. and more. Burgess et al. fail to teach or suggest Applicants' claimed compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet, wherein the dispersion contains particles comprising a DPP-IV inhibitor which is (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt. Instead, Burgess et al. teach Compound A disclosed on page 6 that is completely devoid of Applicants' requisite *adamantyl* moiety. Further, merely because Burgess et al. discloses "...disintegrants, for example, sodium starch glycolate and silicates..." is not sufficient reason or motivation for one skilled in the art to substitute the crosscarmellose sodium in the non-relevant nateglinide tablet of Balkan et al with sodium starch glycolate. The only reason one skilled in the art would have made such a substitution is through the hindsight obtained by reading Applicants' patent specification. However, hindsight is a tempting but forbidden zone. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 228 USPQ 90, 98 (Fed. Cir. 1985); *see also* MPEP 2145(X.A) (cautioning against resort to impermissible hindsight). Accordingly *a prima facie* case of obviousness based on Balkan et al. in view of Burgess et al. under 35 USC 103(a) has not been established and withdrawal of this ground of rejection is respectfully requested.

Claim 76 is rejected under 35 USC 103(a) as obvious over Balkan et al., Burgess et al. and further in view of Koike (US 2004/0033258 A1). The rejection is respectfully traversed. The rejection fails for the same reasons discussed above for Balkan et al., Burgess et al. and more. Koike et al. teaches pharmaceutical preparations containing additives which are preferably not more than 500 µm which causes little or no roughness in the oral cavity. Koike fails to teach or suggest Applicants' claimed compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet, wherein the dispersion contains particles comprising a DPP-IV inhibitor which is (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form. Koike further fails to disclose Applicants' claimed compressed tablet containing (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine wherein at least 60% of the particle size distribution in the tablet is less than 250 µm. Only with impermissible hindsight obtained by reading Applicants' patent specification would one

skilled in the art be able to obtain Applicants' claimed invention. Accordingly *a prima facie* case of obviousness based on Balkan et al., Burgess et al. and further in view of Koike under 35 USC 103(a) has not been established and withdrawal of this ground of rejection is respectfully requested.

If the Examiner has further questions, please contact the undersigned at his or her earliest convenience.

Respectfully submitted,

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